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Amdt. Dated: July 5, 2007
Reply to Office Action Dated: April 5, 2007

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REMARKS

Claims 1, 7-12, 15, 16, 21-22 and 25-29 are pending in the present application. Claims 1, 16, 26, and 28 have been amended. Support for the foregoing amendment can be found throughout the specification and claims as originally filed, for example on page 6, paragraph [0023]. As such, no new matter enters by way of the foregoing amendment.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks.

I. Preliminary Remarks

Prior to addressing the rejections of record, a brief description of the disclosure is provided for the convenience of the Examiner. As described in WO 99/23150, there are problems associated with the addition of anti-microbials to cyanoacrylate monomers:

A problem has arisen in the use of these prepolymer cyanoacrylate ester compositions. Particularly, when some antimicrobial agents are added to the composition, it has been found that premature polymerization or inhibited polymerization occurs. For instance, as disclosed in U.S. Serial No. 08/912,681 filed August 18, 1997 [now U.S. Patent No. 6086906], some antimicrobial agents were found not to be compatible with the polymerizable cyanoacrylate monomer compositions, e.g. tetracycline hydrochloride. First, some antimicrobial agents were not soluble or dispersible in the cyanoacrylate monomer composition at the concentrations necessary to effect antimicrobial properties. Second, some antimicrobial agents employed caused premature polymerization of the cyanoacrylate monomer compositions. Third, some antimicrobial agents employed prevented *in situ* polymerization for the cyanoacrylate monomer composition when applied to the skin, i.e., the composition did not cure. For example, it was found that elemental iodine (I₂) was only partially soluble in the polymerizable cyanoacrylate composition and prevented polymerization. Finally, some antimicrobial agents were not compatible with the intended use of the polymeric film because they inhibit formation of a flexible, durable film. Other antimicrobials caused premature polymerization, e.g., tetracycline hydrochloride caused polymerization within 24 hours of addition.

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Because of these disparate properties, many conventional antimicrobial agents were found to be unsuitable for use in polymerizable cyanoacrylate compositions.

See Page 4, WO 99/23150. The presently claimed monomeric adhesive composition includes a polymerizable monomer and specific antimicrobial agents that ameliorate the foregoing issues in combining such ingredients.

II. Withdrawn Rejections and Finality of Office Action

Applicants acknowledge and thank the Examiner for indicating that the rejection of claims 1-29 on the grounds of nonstatutory double patenting had been withdrawn with respect to the rejections in view of WO 97/32613 or U.S. Patent 5,800,803.

The Examiner alleges, however, that "Applicant's amendment necessitated the new grounds of rejection presented in this Office Action." *Final Action*, at page 22. The Examiner then states that "[a]ccordingly, THIS ACTION IS MADE FINAL." *Id.* Applicant respectfully submits that the finality is improper for at least the following reasons.

The MPEP provides that a "second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)." MPEP § 706.07(a). One of the "new grounds" forwarded by the Examiner in the present application was a non-statutory double patenting rejection, of claims 1, 7-12, 15, 16, 21, 22, and 25-29. The rejection was based on U.S. Patent Nos. 6,579,469, 6,585,967, 6,767,552, 6,602,496, and 6,942,875, each in view of U.S. Patent No. 5,800,803. *Final Action*, at pages 5-6. This is the same double patenting rejection made by the Examiner on page 3 in the Office Action dated October 10, 2006, with the addition of the secondary reference U.S. Patent No. 5,800,803. However, the '803 reference was cited by the Examiner in another double patenting rejection in that same Office Action, for the same proposition used in the Final Action. As such, Applicant's amendments did not necessitate the new grounds of rejection.

Accordingly, Applicant requests reconsideration and withdrawal of the finality of the instant office action.

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III. Double Patenting Rejections

Claims 1, 7-12, 15, 16, 21, 22, and 25-29 are rejected for nonstatutory obviousness-type double patenting over all of the claims of U.S. Patent Nos. 6,579,469, 6,585,967, 6,767,552, 6,602,496, and 6,942,875, each in view of U.S. Patent No. 5,800,803. *Final Action*, at page 5. This rejection is obviated by amendment to the claims. In particular, none of the currently claimed anti-microbial agents are recited in any of the claims of the foregoing patents. Moreover, it would not have been obvious to select the currently claimed anti-microbial agents in view of the recognized problems associated with the addition of antimicrobials to cyanoacrylate monomers such as those disclosed in WO 99/23510, for example, that teaches that "when some antimicrobial agents are added to the [prepolymer cyanoacrylate ester] composition, it has been found that premature polymerization or inhibited polymerization occurs." PCT Publication No. WO 99/23150 at page 4, lines 10-13. Accordingly, it respectfully requested that the Examiner withdraw this rejection.

Claims 1, 7-12, 15, 16, 21, 22, and 25-29 stand provisionally rejected for nonstatutory obviousness-type double patenting as allegedly being unpatentable over copending applications 10/355,294 and 10/429,050, each in view of U.S. Patent No. 5,800,803. *Final Action*, at page 6. Applicants note that both of the applications cited by the Examiner are identified in the U.S. Patent Office's PAIR system as abandoned, and as such, are no longer co-pending. As the cited applications are no longer co-pending, there are no conflicting claims with the instant application. Accordingly, applicants request reconsideration and withdrawal of the nonstatutory obviousness-type double patenting rejection over U.S. Application Nos. 10/355,294 and 10/429,050.

IV. Claim Rejections Under 35 U.S.C. § 112, Enablement

Claims 1-29¹ have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way so as to enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. *Final Action* at pages 8-11. Applicants respectfully disagree.

The amended claims are directed to monomeric adhesive compositions and methods of making and using such compositions having polymerizable cyanoacrylate monomers and an antimicrobial agent selected from the recited list of halogenated phenolic active

¹ Applicants note that the reference to claims 1-29 appears to be a typographical error, as claims 1, 7-12, 15, 16, 21, 22, and 25-29 are pending in the instant application.

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compounds. The recited halogenated phenolic compounds include parachlorometaxylenol, p-chlorophenol, 2-chlorophenol, 3-chlorophenol, 4-chlorophenol, 2,4-dichlorophenol, 2,4,6-trichlorophenol, 2,3,4,6-tetrachlorophenol, pentachlorophenol, 4-chlororesorcinol, 4,6-dichlororesorcinol, 2,4,6-trichlororesorcinol, cyclohexyl p-chlorophenol, o-benzyl-m-methyl p-chlorophenol, o-benzyl-m,m-dimethyl p-chlorophenol, o-phenylethyl p-chlorophenol, o-phenylethyl-m-methyl p-chlorophenol, dichloro-m-xylenol, 3,4,6-trichlorophenol, 4-chloro-2-phenylphenol, 6-chloro-2-phenylphenol, 2,4-dichloro-3,5-diethylphenol, p-bromophenol, methyl p-bromophenol, ethyl p-bromophenol, n-propyl p-bromophenol, n-butyl p-bromophenol, n-amyl p-bromophenol, sec-amyl p-bromophenol, n-hexyl p-bromophenol, cyclohexyl p-bromophenol, o-bromophenol, tert-amyl o-bromophenol, n-hexyl o-bromophenol, n-propyl-m,m-dimethyl o-bromophenol, 2,2'-methylene bis (4-chloro-6-bromophenol), and mixtures thereof.

The Examiner acknowledges that the specification is "enabling for composition [sic] comprising octyl-cyanoacrylate monomer and triclosan," however goes on to allege that the specification "does not reasonably provide enablement for all the polymerizable monomers and all the antimicrobial agents, and all the phenolic compounds." *Final Action* at page 8.

Contrary to the Examiner's assertion, Applicants need not enable "all polymerizable monomers and all the antimicrobial agents, and all the phenolic compounds." Rather, Applicants need only enable the claimed invention. Applicants have provided considerable direction and guidance such that it is well within the level of ordinary skill in the art to practice the claimed invention without undue burden. For example, the specification discusses polymerizable cyanoacrylate monomers, and methods of preparing such monomers. *See, Specification*, at paragraphs [0035] through [0040]. In addition, the specification discusses numerous antimicrobial agents, including the recited compounds for use in the claimed compositions. *See, e.g., Specification*, at paragraphs [0022] through [0023]. As the Examiner recognizes, the specification also provides a working example of a composition containing a cyanoacrylate monomer, 2-octyl cyanoacrylate, and an antimicrobial agent, triclosan. Although the exemplified composition does not contain one of the antimicrobial agents recited in the claims, the example provides additional guidance to the skilled artisan to make the claimed compositions. Furthermore, the "specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation." MPEP § 2164.02 (citing *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)). Taken in combination,

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the disclosure provides adequate guidance and direction to those skilled in the art of how to make and use the claimed invention.

The Examiner also argues that “the practitioner would turn to trial and error experimentation to practice the instant invention directed to composition comprising polymerizable monomer and antimicrobial agent, and method of its making....” *Final Action*, at page 11. The MPEP states “[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.” MPEP § 2164.01 (citing *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976)). In addition, “the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.” *Id.* (citing *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985)).

Accordingly, the specification enables the claimed invention without undue experimentation. Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 112, first paragraph.

V. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 7, 12, and 21 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly failing to particularly point out and distinctly claim the subject matter. In particular, the Examiner alleges that “[t]he expression “substantially” does not set forth the metes and bounds of the claim.” *Final Action* at page 12. Applicants respectfully disagree for at least the following reasons.

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. MPEP § 2173. Applicants submit that the meaning of the term “substantially” is clear when read in the context of the specification. For example, the skilled artisan would readily understand the meaning of the term “substantially” based on the present disclosure. The specification discloses, with respect to the antimicrobial agents’ affect on the polymerization rate, that, for example, “the polymerization rate of the monomer composition with the antimicrobial agent should preferably differ from the polymerization rate of a comparable monomer composition with the anti-microbial agent by no more than about 50%, preferably no more than about 20%.” *See, Specification*, at paragraph [0020]. In

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addition, the specification further discloses that the "stability of the monomer composition is maintained for a period of time sufficient to provide a commercially significant shelf-life to the monomer composition, or even an extended shelf-life as compared to similar monomer composition not including such an agent." *See, Specification*, at paragraph [0026]. Based on such disclosure, the skilled artisan would readily understand the meaning of the term. Accordingly, Applicants believe that claims 7, 12, and 21 are definite and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

VI. Claim Rejections Under 35 U.S.C. § 102

A. U.S. Patent No. 6,455,033

Claims 1, 7-12, 16, 21-22, and 28-29 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,455,033 (hereinafter the "033 Patent").

Final Action at pages 13. Applicants respectfully traverse for at least the following reasons.

Initially, Applicants note that the recitation of o-benzoyl-p-chlorophenol has been deleted from the group of antimicrobial compounds in claims 1, 16, 26, and 28. As such, amended claims 1, 16, 26, and 28 are directed to monomeric adhesive compositions, methods of making and methods of applying compositions comprising a polymerizable cyanoacrylate monomer and an antimicrobial agent selected from the amended Markush group.

The Examiner has not argued that the '033 Patent discloses compositions other than "curable polymerizable monomer and antimicrobial o-benzoyl-p-chlorophenol compound." Accordingly, since the cited reference does not anticipate independent claims 1, 16, 26, and 28 neither does it anticipate the claims dependent thereon. As such, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102.

VII. Claim Rejections Under 35 U.S.C. § 103

A. Statement of Common Ownership

Claims 1, 7-12, 16, 21, 22, 26, 28, and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over, *inter alia*, U.S. Patent No. 6,579,469, U.S. Patent No. 6,585,967, U.S. Patent No. 6,602,496, U.S. Patent No. 6,942,875, U.S. Publication No. 2004/0223946, and U.S. Publication No. 2004/0151688. The Examiner states that this "rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C 103(c) as prior art in a rejection under 35 U.S.C. 103(a)." *Final Action*, at page 21 (citing MPEP § 706.02(l)(1) and § 706(l)(2)).

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The instant application and U.S. Patent Nos. 6,579,469, 6,585,967, 6,602,496, and 6,942,875, and U.S. Publication Nos. 2004/0223946, and 2004/0151688 were, at the time the invention of the instant application was made, owned by, or were subject to an obligation of assignment to Closure Medical Corp. As such, U.S. Patent Nos. 6,579,469, 6,585,967, 6,602,496, and 6,942,875, and U.S. Publication Nos. 2004/0223946, and 2004/0151688 are disqualified from being used in a rejection under 35 U.S.C. § 103(a) against the claims of the instant application. *See, MPEP § 706(l)(2).*

B. Rejections of Claims 1, 7-12, 16, 21, 22, 26, 28, and 29

Claims 1, 7-12, 16, 21, 22, 26, 28, and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over any of WO 99/23510, U.S. Patent No. 6,281,265, U.S. Patent No. 6,310,166, U.S. Patent No. 6,352,704, U.S. Patent No. 6,579,469, U.S. Patent No. 6,585,967, U.S. Patent No. 6,602,496, U.S. Patent No. 6,942,875, U.S. Publication No. 2004/0223946, and U.S. Publication No. 2004/0151688, each in view of 5,800,803. *Final Action* at page 14. Applicants respectfully traverse for at least the following reasons.

The Examiner acknowledges that "each of the references does not teach the specification antimicrobial agents as claims by claim 1." *Final Action* at page 16. However, the Examiner asserts that "US '803 teaches antibacterial agents that are [sic] showed increased uptake to the dental tissues when combined with acrylate polymers, such antibacterial agents include chlorinated and brominated phenol compounds." *Id.* The Examiner therefore concludes that

...it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of WO '150, US '265, US '166 or US '704, US '469, US '967, US '496, US '875, US '946, US '688 and replace the antimicrobial agent by brominated phenol compounds disclosed by US '803, motivated by the teachings of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and brominated phenol compounds that has effective antimicrobial effect at the site of application.

Final Action at page 17.

However, the Examiner has provided no support for why a skilled artisan would have made such compositions in view of the disclosure of WO 99/23510, for example, that teaches that "when some antimicrobial agents are added to the [prepolymer cyanoacrylate ester]

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composition, it has been found that premature polymerization or inhibited polymerization occurs." PCT Publication No. WO 99/23150 at page 4, lines 10-13. The Examiner must provide reasons why the skilled artisan would modify the cited references to arrive at the currently claimed compositions in view of the teachings of WO 99/23150. *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. ____ (2007).

The present claims are directed to monomeric adhesive compositions comprising a polymerizable cyanoacrylate monomer and one of the recited antimicrobial agents. The '803 patent cited by the Examiner is directed to oral compositions exhibiting increased uptake by dental tissues of antibacterial compounds containing copolymers of hydrophilic monomers having an alkyl-group that contains 1-30 carbon atoms, preferably 1 to 8 carbon atoms, such as methylacrylate. The Examiner has provided no reasons for why a skilled artisan would combine the disclosures of any of WO 99/23510, U.S. Patent No. 6,281,265, U.S. Patent No. 6,310,166, U.S. Patent No. 6,352,704, U.S. Patent No. 6,579,469, U.S. Patent No. 6,585,967, U.S. Patent No. 6,602,496, U.S. Patent No. 6,942,875, U.S. Publication No. 2004/0223946, and U.S. Publication No. 2004/0151688 with the teachings of U.S. Patent No. 5,800,803 to obtain the instantly claimed invention.

Accordingly, the claims are not obvious over any of WO 99/23510, U.S. Patent No. 6,281,265, U.S. Patent No. 6,310,166, U.S. Patent No. 6,352,704, U.S. Patent No. 6,579,469, U.S. Patent No. 6,585,967, U.S. Patent No. 6,602,496, U.S. Patent No. 6,942,875, U.S. Publication No. 2004/0223946, and U.S. Publication No. 2004/0151688. Thus, Applicants respectfully request that the rejections of claims 1, 4, and 5 under 35 U.S.C. § 103(a) be withdrawn.

C. Rejection of Claims 15, 25, and 27

Claims 15, 25, and 27 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the combination of any of "WO 150, US '265, US '033, US '875, US '688 each in view of US '803, and further in view of US '166." *Final Action* at page 17. Applicants respectfully traverse for at least the following reasons.

The Examiner argues that "[t]he combined teachings of WO 150, US '265, US '033, US '875, or US '688 each with US '803 are discussed above." *Final Action*, at page 17. The Examiner goes on to argue that "the combination of references do not teach the composition is sterile, which is taught by US '166." *Id.* However, the Examiner still has not shown that

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the combined references disclose or suggest all of the antimicrobial agents recited in the claims from which claims 15, 25, and 27 depend.

Again, as discussed above, the Examiner has not provided any support for why a skilled artisan would have made the compositions recited in the independent claims in view of the disclosure of WO 99/23510, for example, that teaches that "when some antimicrobial agents are added to the [prepolymer cyanoacrylate ester] composition, it has been found that premature polymerization or inhibited polymerization occurs." PCT Publication No. WO 99/23150 at page 4, lines 10-13.

Accordingly, claims 15, 25, and 27 are not obvious over any of WO 99/23510, U.S. Patent No. 6,281,265, U.S. Patent No. 6,455,033, U.S. Patent No. 6,942,875, U.S. Publication No. 2004/0151688 each in view of US Patent No. 5,800,803, and further in view of U.S. Patent No. 6,310,166. Thus, Applicants respectfully request that the rejections of claims 15, 25, and 27 under 35 U.S.C. § 103(a) be withdrawn.

D. Rejection of Claim 27

Claim 27 has been rejected under 35 U.S.C. § 103(a) as allegedly "unpatentable over US '469 in view of US '166." *Final Action* at page 18. Applicants respectfully traverse for at least the following reasons.

The Examiner alleges that "it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agents as disclosed by any one of WO '150, US '265 [sic], and further sterilize the composition by heat or gamma irradiation as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity." *Id.*

Again, as discussed above, the Examiner has not provided any support for why a skilled artisan would have made the compositions recited in the independent claims in view of the disclosure of WO 99/23510, for example, that teaches that "when some antimicrobial agents are added to the [prepolymer cyanoacrylate ester] composition, it has been found that premature polymerization or inhibited polymerization occurs." PCT Publication No. WO 99/23150 at page 4, lines 10-13.

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As such, claim 27 is not obvious over U.S. Patent No. 6,579,469 in view of U.S. Patent No. 6,310,166. Thus, Applicants respectfully request that the rejection of claim 27 under 35 U.S.C. § 103(a) be withdrawn.

E. Rejection of Claims 1, 7-12, 16, 21, 22, and 28-29

Claims 1, 7-12, 16, 21, 22, and 28-29 have been rejected under 35 U.S.C. § 103(a) as allegedly "obvious over US 6,455,064 ('064) or US 6,746,667 ('667) each in view and [sic] US '803." *Final Action* at page 18. Applicants respectfully traverse for at least the following reasons.

The Examiner alleges that "[t]he references teach polymer composition comprising cyanoacrylate and antimicrobial agent for wound closure." *Id.* The Examiner goes on to argue that "[t]he references do not teach chlorophenol and bromophenol as antimicrobial agents in the composition, which are disclosed by US '803." *Id.* The Examiner concludes that the combination is obvious because the skilled artisan would have been "motivated by the teaching of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with [a] reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or brominated phenol compounds that has effective antimicrobial effect at the site of application." *Id.* at page 19.

Again, as discussed above, the Examiner has not provided any support for why a skilled artisan would have made the compositions recited in the independent claims in view of the disclosure of WO 99/23510, for example, that teaches that "when some antimicrobial agents are added to the [prepolymer cyanoacrylate ester] composition, it has been found that premature polymerization or inhibited polymerization occurs." PCT Publication No. WO 99/23150 at page 4, lines 10-13.

As such, claims 1, 7-12, 16, 21, 22, and 28-29 are not obvious over U.S. Patent No. 6,455,064 or US 6,746,667 in view of U.S. Patent No. 5,800,803. Thus, Applicants respectfully request that the rejection of claims 1, 7-12, 16, 21, 22, and 28-29 under 35 U.S.C. § 103(a) be withdrawn.

F. Rejection of Claims 15 and 25- 27

Claims 15 and 25-27 have been rejected under 35 U.S.C. § 103(a) as allegedly "obvious over any of US '064 and US '667 each in view of US '803 and further in view of

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US '166.' *Final Action* at page 19. Applicants respectfully traverse for at least the following reasons.

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Again, as discussed above, the Examiner has not provided any support for why a skilled artisan would have made the compositions recited in the independent claims in view of the disclosure of WO 99/23510, for example, that teaches that "when some antimicrobial agents are added to the [prepolymer cyanoacrylate ester] composition, it has been found that premature polymerization or inhibited polymerization occurs." PCT Publication No. WO 99/23150 at page 4, lines 10-13.

As such, claims 15 and 25-27 are not obvious over U.S. Patent No. 6,455,064 or US 6,746,667 in view of U.S. Patent No. 5,800,803 and further in view of U.S Patent No. 6,310,166. Thus, Applicants respectfully request that the rejection of claims 15 and 25-27 under 35 U.S.C. § 103(a) be withdrawn.

VIII. Conclusion

For the foregoing reasons, claims 1, 7-12, 15, 16 21, 22, and 25-29 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

HUTCHISON LAW GROUP PLLC

By: 

Thomas E. Holsten
 Registration No. 46,098

Date: July 5, 2007

P.O. Box 31686
 Raleigh, NC 27612
 +1.919.829.9600

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Diana Martin
 (Typed Name of Person Signing Certificate)

Diana Martin
 (Signature of Person Signing Certificate)

Date of Signing: July 5, 2007